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Moving Science and Technology Policy Forward: The Role of Congress

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MOVING SCIENCE AND TECHNOLOGY POLICY FORWARD: THE ROLE OF CONGRESS

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My Article focuses solely on Food and Drug Administration (FDA) reform legislation. Since I joined Senator Barbara Mikulski's staff about four months ago, FDA reform has been my major focus. However, I have worked on several other issues ranging from health insurance reform to the National Institutes of Health to Medicare and Medicaid.

Senator Mikulski is greatly sympathetic to the needs of the biotechnology industry. She believes that the members of the industry are saving lives, saving jobs, and are very much on the cutting edge of research. She is absolutely committed to passing an FDA reform bill this year.[1]

Senator Mikulski's relationship with the biotechnology industry predates my time on her staff. She became acquainted with many of the leaders in the field through the BIO national organization during the health care reform debate.[2] At that time, she learned how biotechnology products differ from

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1. Redefines the FDA's mission (*see infra* note 17), reduces unnecessary regulatory burdens, supports creativity and the entrepreneurial spirit in the biotech industries, reduces demands which place burdens on research and development, and balances safety considerations while rewarding efficiency and competitiveness. *Senate Holds 2 Days of Controversial Hearings on FDA Reform, Settles Nothing,* 6 BIOMEDICAL MARKET NEWSL., Feb. 1, 1996.

2. Clinton health care reform, debated in the Senate from 1992-1994, was embodied in the American Health Security Act, H.R. 3600, S. 1757, Health Care Security, Calendar No. 335, 103d Cong., 1st Sess. (1993). Mark V. Pauly, *The Impact of Health Reform on the Pharmaceutical Industry,* 24 SETON HALL L. REV. 1271, 1271 n.1 (1994). *See also* Henry Grabowski, *Health Reform and Pharmaceutical Innovation,* 24 SETON HALL. L. REV. 1221 (1994). *See also* Andrew S. Krulwich, *The Response to Health Care Reform by the Pharmaceutical Industry,* 50 FOOD AND DRUG L.J. 1 (1995).

pharmaceuticals produced by the large pharmaceuticals companies.[3] This led her to become a champion of regulatory reform for the biotechnology industry. Last year, for example, she joined forces with Vice President Gore, Senator Kennedy, and BIO to support the Reinventing Government initiative that would streamline the regulatory process for biotechnology products.[4] This initiative would eliminate the establishment licensing application,[5] lot release requirements,[6] and excessive paper work requirements.[7]

Senator Mikulski also supported an FDA Reform Export bill,[8] which passed the Labor Human Resources Committee last year.[9] The bill is part of our FDA reform bill in the Senate,[10] but President Clinton just signed the

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3. Biotechnology drugs come from living things, thereby falling under regulations governing "biologics" such as blood. These regulations are harder to meet than pharmaceutical regulations, though biotech drugs can be treated like other drugs without affecting safety, according to the FDA Commissioner. David A. Kessler & John Schwartz, *FDA Revises Biotechnology Rules; Changes are Designed to Consolidate and Speed Approval Process*, WASH. POST, Nov. 13, 1995, at A19.

4. President Clinton announced his proposed reforms for the FDA on March 16, 1995:

> Today we are announcing a set of reforms that will make our high-quality drugs and medical devices available to consumers more quickly and more cheaply. First, FDA will stop using a full-blown review every time a biotech company makes a minor and risk-free manufacturing change in an established drug.
>
> Second, FDA will stop requiring costly assessments on drugs that obviously have no significant impact on the environment.
>
> Third, FDA will eliminate 600 pages of cumbersome regulations controlling the production of antibiotics and other drugs. . . . And finally, 140 categories of medical devices that pose low risk to patients, from finger exercisers to oxygen masks, will no longer need approval by the FDA before they are put on the market.

President's Remarks on Regulatory Reform in Arlington, Virginia, 31 WKLY. COMP. PRES. DOC. 426 (Mar. 16, 1995). *See also* Teresa Pechulis Buono, *Biotechnology-Derived Pharmaceuticals: Harmonizing Regional Regulations*, 18 SUFFOLK TRANSNAT'L L. REV. 133 (Winter 1995).

5. Separate applications must be filed for each (even understood) new biotech drug whereas a single license is required for manufacturers of pharmaceuticals. The Food, Drug and Cosmetic Act § 262(a) required establishment license applications (ELAs) separate from product license applications (PLAs) required by § 262(d)(1). Edward L. Korwek, *Human Biological Drug Regulations: Past, Present, and Beyond the Year 2000*, FOOD AND DRUG L.J. 123, 125 (Special Issue 1995).

6. Biotech manufacturers must seek approval for each lot of biotech drugs shipped. *Id.* at 128-35; *see generally* sections B and C, "Provisions of the Federal Food Drug and Cosmetic Act Applied to Biologics," and "Differences in Regulations Between Biological Drugs and Other Drugs."

7. Biotech drug approvals currently require 21 separate applications, which would be consolidated into one. 21 C.F.R. §§ 601.1, 601.2, and 601.3 are regulatory burdens cited in a 1996 study of the regulatory reform needed in biotechnology. These regulations related to separate product license applications requirements. But, in general, all of the 21 C.F.R. § 600 regulations were identified as problems, especially §§ 620-680, which are particularly burdensome. Bogdan Dzinrzynski, *FDA Regulatory Review and Approval Process: A Delphi Inquiry*, 51 FOOD AND DRUG L.J. 143, 150-51 (1996).

8. S. 593, 104th Cong., 1st Sess. (1995).

9. S. 593 was reported out of committee on August 2, 1995.

10. Food and Drug Administration Performance and Accountability Act of 1995. A bill to amend the federal Food, Drug, and Cosmetic Act, and the Public Health Service Act to improve the regulation of food, drugs, devices and biological products, and for other purposes. Introduced 12-13-95. S. 1477, 104th Cong., 1st Sess. (1995).

Export Reform measures as part of the omnibus appropriations bill that finally went through.[11]

In spite of these measures, however, Senator Mikulski believes that the regulatory reforms within the administration and within the FDA simply are not enough by themselves to accomplish what really needs to be done. The Senator is firmly committed to moving the FDA into the 21st century; she wants a new legislative and regulatory framework for the agency, one that would lift unnecessary regulatory burdens, one that really changes the culture of the FDA.[12] She strongly believes that yesterday's regulations, and members of the industry certainly can relate to this, do not fit the science of today and tomorrow.

One of the points we felt very strongly about as we worked on the bill in the Senate was that the FDA must define its mission. Born out of the "snake-oil days,"[13] the FDA has always been deemed the protector of public health; however, it has never really focused on how to get products to the market quickly. How do we quickly get new products to patients? How do we advance public health? Because distribution is important to the public health, our legislation made clear that we must not only try to protect public health and safety, but we must also advance public health through the developments and the products generated by the biotechnology industry.

Since I joined the Senator's staff in January, I have experienced a very quick learning curve due to the fact that we had our hearings on FDA reform in February. I had to quickly learn everything one could know about the FDA. In my prior life, I worked for Medical Research Specialty Societies and worked with the FDA on OBGYN related drugs and devices, but that constituted only a small exposure to FDA procedures.

To get myself, as well as the Senator, up to speed concerning which issues are of concern to the biotechnology industry, we held two round tables

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11. Signed April 25, 1996.

12. Elimination of the requirement that drug companies conduct two clinical efficacy studies on drugs; FDA Commissioner term limits; reform of animal drug approval requirements; simplification of the food additive process, such as making clear distinctions between direct and indirect food additives; uniform standards for issuance of policy statements; and establishment of performance standards. S. 1477, 104th Cong., 1st Sess. (1995).

New technologies are a *process*, not a product. Traditional drug development regulation may not be appropriate. Martha J. Carter, *The Ability of Current Biologics Law to Accommodate Emerging Technologies*, 51 FOOD AND DRUG L.J. 375, 378-79 (1996). *See also* John Cady, *FDA Reform: The Need for a Sound Science-Based Approach*, 51 FOOD AND DRUG L.J. 407 (1996). *See also* David A. Kessler, *Remarks by the Commissioner of Food and Drugs*, 51 FOOD AND DRUG L.J. 207 (1996). The guiding principles of the Food and Drug Administration are safety and efficacy. *Id.* at 214. *See also* John C. Petricciani, *Reinventing the Biologics Approval Process*, 51 FOOD AND DRUG L.J. 139 (1996). The approval process of new medical products should account for the highly interdependent nature of the administratie systems. There may be no easy way to simplify the process, without reexamination of the FDA's structure, function and process. *Id.* at 142.

13. June 24, 1938, ch. 675, § 903, 52 Stat. 1040, appearing as 21 U.S.C.S. § 393(a). *See* Vincent A. Kleinfeld, *Legislative History of the Federal Food, Drug, and Cosmetic Act*, FOOD AND DRUG L.J. 65 (Special Issue 1995). The history begins with the Food and Drugs Act of 1906 (34 Stat. 768) and continues with the FDCA of 1938.

in the State of Maryland, one in Baltimore and one in Montgomery County. Bob Eaton[14] was involved in these. The purpose of these round tables was for the Senator to meet representatives of the biotechnology industry and learn what concerns the companies had. Those meetings were extremely informative and helped us come together with some ideas that we wanted to get in the reform bill and Senator Kassebaum's FDA reform bill.[15]

Repeatedly, we heard that the biotechnology industry does want the FDA, and that they want a strong FDA. None of the companies said that they do not want to be regulated, that they do not want the FDA. What they did say, however, was that the FDA is a great source of frustration to them as they try to have their products reviewed and approved for the market.

We heard many horror stories—and the Senator is keen on anecdotes, which help her form her legislative platform. For example, one company said it took nine months for the FDA to answer a simple question. In the meantime, the company was afraid to move forward because of fear of retaliation from the FDA. Another company said that it took two years to get approval for a minor manufacturing change.

Of major concern to the Senator was the fact that many companies were thinking about moving their manufacturing facilities abroad—and of course, with them go American jobs. Thus, the Senator did not need much convincing that FDA reform was needed in order to stop this.

Senator Mikulski's FDA reform is based on two principles: she wants to see public health and safety protected, and she also wants to reward efficiency and competitiveness. This is why the Senator voted for the Kassebaum reform bill, which passed the Senate Labor and Human Resources Committee at the end of March.[16] Senator Kassebaum's bill establishes a strong mission statement for the FDA.[17] It focuses not only on safety and efficacy, but it also, for the first time ever, requires the FDA to facilitate and work with companies to get products to the market quickly, safely, and

14. Bob Eaton is Chairman and CEO of Chrysler Corporation.

15. S. 1477, 104th Cong., 1st Sess. (1995).

16. That bill came out of committee on March 28, 1996 with strong bipartisan support. We had twelve voting in favor, and four opposed.

17. To promote and protect the public health by "(1) facilitating the rapid and efficient development of articles subject to the regulation of the administration; (2) protecting the public from unsafe or ineffective articles subject to the regulation of the administration; (3) enforcing the applicable statutes and regulations in a timely, fair, consistent, and decisive manner." S. 1477, 104th Cong., 1st Sess. § 102 (1995).

expeditiously.[18] The bottom line of this FDA reform is that it helps patients and improves the general public health.

The bill also establishes quantifiable performance standards for reviewing drugs and devices, while making the FDA accountable to Congress.[19] The bill requires the FDA to inform us how they are meeting the deadlines that are laid out in the bill. The bill also contains statutory deadlines for product approvals.[20]

An outstanding accomplishment of this bill is that it credits a high degree of collaboration between the private biotechnology industry and the FDA. In fact, I jokingly call this bill the "FDA Industry Communications Bill," because it requires a number of meetings between the FDA and members of the biotechnology industry.[21] In one of our draft versions, we had even specified telephone calls, but then we thought that went a little too far toward micro-managing, so we dropped some of those provisions.

We hope that this early collaboration will reduce the frustration the industry felt in terms of getting responses from the FDA. The Senator firmly believes that members of the industry have a right to know where they are in the process and where things are going; they should not be stonewalled in their efforts. One of the things the biotechnology companies revealed in our meetings[22] was their fear that they would invest the time and money to

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18. The bill mandates:

> (1) performance standards for FDA reviews under the Act and actions relating to advisory committees;
> (2) collaboration between the FDA, The National Institutes of Health, and other Federal science-based agencies;
> (3) an information system accessible by applicants, petitioners, and persons submitting notifications; and
> (4) a procedure regarding policy statements of general applicability.

S. 1477, 104th Cong., 1st Sess., § 103 (1995).

19. *Id.*

20. For example, under S. 1477, 104th Cong., 1st Sess. (1995), the FDA has 30 days to review investigational new drugs (§ 544); classification of a product into a drug or biological product must be made within 60 days (§ 741); the FDA must eliminate all backlog by January 1, 1998 (§ 103); and the FDA must fully comply with all statutory time deadlines by July 1, 1998 (§ 103).

21. Performance standards are to be set only after broad consultation. S. 1477, 104th Cong., 1st Sess., § 103 (1995). The FDA will consult with science groups and will give public notice of these consultations. S. 1477, 104th Cong., 1st Sess., § 106 (1995). Any person intending to sponsor a drug (including a biological product) may request a meeting with the secretary for a collaborative design review. S. 1477, 104th Cong., 1st Sess., § 544 (1995).

22. The FDA has also been involved in these discussions. About a week before the first proposed mark-up came in, we met one night and they went through the draft bill. They had a concern with every other sentence, which was very frustrating from the staff perspective. I was thinking, and admittedly I was the new kid on the block, "where had they been?" Dr. Kessler, the FDA Commissioner, is still concerned. In fact, during his testimony in the House, he expressed concerns about the House bills.

The FDA continues to be involved in the discussions. We have had lists of their concerns ranging from many technical changes to some of the major concerns, the hammer issue, and the third party pilot project issue. In addition to the FDA, the Department of Health & Human Services and the White House are involved. So, it has been difficult to get everyone involved

complete the clinical process, only to have the FDA suddenly say, "No, this isn't the way we want it done." We are hoping that this bill will allay such fears.

To help simplify the FDA process, the bill streamlines data requirements and makes manufacturing changes for biotechnology products.[23] Another issue the Senator supported was the contracting of private companies to perform government work.[24] The Kassebaum bill does permit contracting-out and, in some situations, requires it.[25] Senator Mikulski worked with Senator Kassebaum to strengthen that area of the bill.

Senator Mikulski supported a number of amendments that came up, including one that would establish a pilot project for third party review of medical devices.[26] Although we did get the bill out of committee, there are some warning signs. Many of these problems have been reported in various trade publications, the *Washington Post*,[27] and other newspapers. For example, Senator Kennedy is very concerned that the bill undermines safety and efficacy.

We have been working with Senator Kennedy's staff in order to address some of these issues. For instance, Senator Mikulski was concerned about the manufacturing changes for the biotechnology products. Senator Kennedy wanted to offer an amendment in committee that would eliminate the Arrigo initiative, which was intended to streamline the manufacturing process for biotechnology products. Senator Kennedy proposed making the process into a three-level review. In other words, going backwards instead of forwards. Fortunately, Senator Kennedy eventually agreed to withdraw that amendment. The committee did ask BIO if they would work with the committee, Senator

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at the highest levels of the White House.

23. The bill requires new performance standards to expedite applications for biological products under certain circumstances. S. 1477, 104th Cong., 1st Sess., § 103 (1995). The FDA has 120 days for approve or deny a product under certain serious conditions. S. 1477, 104th Cong., 1st Sess., § 204 (1995). The bill includes provisions for timely review and reasonable data requirements for clinical research. S. 1477, 104th Cong., 1st Sess., § 302 (1995). Section 749 provides for import/export reform of biological products. Title VII of the Bill is entitled "Drug and Biological Products Regulatory Reform," and includes many regulatory revisions. S. 1477, 104th Cong., 1st Sess., § 749 (1995).

24. The Environmental Protection Agency is one agency that contracts work to private companies.

25. The FDA may contract work to outside organizations with special expertise. S. 1477, 104th Cong., 1st Sess., § 742 (1995). If the secretary fails to meet time limits for 95% of products in a certain category, then with the sponsor's consent it must contract with experts during the next fiscal year. S. 1477, 104th Cong., 1st Sess., § 743 (1995).

26. Senator Coats offered an amendment setting up a 3-year pilot program for private third party review of premarket approval applications for devices. The amendment passed by a vote of 11 to 4. S. REP. NO. 284, 104th Cong., 2d Sess (1996).

27. *The FDA Legislation*, WASH. POST, Apr. 10, 1996, at A18; John Schwartz, *FDA Reforms Have Momentum as Hearings Open; At Least 3 Measures Under Consideration, Including One That Allows Private Review of Drugs*, WASH. POST, May 1, 1996, at A8; Morton Mintz, *The Cure That Could Kill You; FDA Reforms Are Bad Medicine*, WASH. POST, July 14, 1996, at C1.

Kassebaum, and the FDA to come up with some changes to that language.[28] BIO is now very close to reaching an agreement with the FDA on that.

We do need to fine-tune this third-party pilot review project. Initially, I thought the FDA would be vehemently opposed to the project because they thought that every single medical device would be reviewed by a third party. Yet this is not exactly the case. I recommended that Senator Mikulski support this amendment because it allows the FDA to remain in control and retain final decision-making authority. It was important to Senator Mikulski that the FDA retain such control; however, the amendment requires the FDA to accredit third-party review organizations.[29] These organizations would have to protect proprietary secrets, remain free of conflicts of interest, and maintain certain safety and efficacy standards.[30] The device companies would then pay these parties to conduct their reviews. The recommendations resulting from the reviews would then go to the FDA, which would make the final decision. The FDA would pick two or three of these accrediting organizations and assign them to a company. The company would then choose which one they wanted to use.

There has been much criticism of this procedure. The FDA thinks that every single medical device must be reviewed by a third party organization; that was never our intent. The whole idea was merely a pilot project scheduled to last for three years. This project is experimental and, by its very nature, will have to be limited in scope.

Many people also seem to be concerned about the hammer mechanisms in the bill.[31] These hammer mechanisms provide that if the FDA does not meet the statutory time frames in the bill, then at least 95% of their work must to be contracted out to private enterprise.[32] The FDA is very concerned about these provisions, as is Senator Kassebaum's office and all the other Democrats with whom we have been working—but no one seems to be able to come up with a better proposal.

The final warning sign is the off-labeling provisions,[33] which permit the dissemination of information to the general public.[34] Senator Mikulski

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28. S. 1477, 104th Cong., 1st Sess. (1995).

29. S. REP. NO. 284, 104th Cong., 2d Sess. 64 (1996).

30. *Id.*

31. Section 403 of the bill would amend Chapter VII of the FDCA to add a new section 742 on contracts for expert review. S. 1477, 104th Cong., 2d Sess., § 403 (1995).

32. S. REP. NO. 284, 104th Cong., 2d Sess. (1996).

33. When the FDA approves a new drug, that approval applies only to the uses for which the manufacturer has demonstrated the drug's safety and effectiveness to the FDA's satisfaction. Sarah F. Jagger, *Hearings Before the Subcommittee on Human Resources and Intergovernmental Relations*, 104th Cong., 2d Sess. 2 (1996). An "off-label" use of a drug occurs when a physician prescribes an FDA-approved drug for treatments other than those specified on the label. *Id.*

34. Currently, the FDA does not regulate a physician's access to information about off-label uses of a drug. Michael Friedman, *Hearings Before the Subcommittee on Human Resources and Intergovernmental Relations*, 104 Cong., 2d Sess. 13 (1996). However, a manufacturer may not promote and distribute information about an off-label use of a drug unless specifically requested by a physician. *Id.* Provisions relating to the dissemination of information about off-label uses

supports such provisions. Right now, there is much disagreement and no unified position within the pharmaceutical industry, so we must continue to resolve that rift. After the bill was reported out of committee, our staff immediately began meeting with the Democrats who supported the bill.[35] We have all been meeting together as staff, and have dubbed ourselves the "Sensible Center Coalition."

We recently had several meetings with the Clinton Administration. This morning, we had some really good news from his administration. They are firmly behind FDA reform. Secretary Shalala came in this morning and met with Senator Mikulski, and told us that President Clinton is firmly behind FDA reform. They are focusing on their major concerns and not giving us a litany of five-thousand concerns. They are open to compromise and are willing to be flexible. This is very good news because we certainly would like to get more bipartisan support, more Democrats on the bill. We would like to get the Administration's support because it would do no good to get a bill through Congress, only to have it vetoed by the President. Thus, we have had to do a lot of compromising.

Senator Kassebaum and her staff have been a joy to work with throughout this entire process. I really believe that we are going to get an FDA reform bill this year. For every bill that comes out of committee, a report is filed which specifies Congressional intent in the statutory language. The report for this bill is one-hundred pages of single-space type. The report will be filed three days after the bill goes to the floor.[36] We are not quite ready to get to the floor because we have to do our background work and get more supporters. We will certainly be counting on BIO and the biotechnology industry to help us do that.

I have heard that Senator Kassebaum would like the bill to come to the floor in June and this morning in her conversation with Secretary Shalala, Senator Mikulski said she wants to come even quicker if that is at all possible. Senator Mikulski would really like to see the senate bill be the first bill reported. I hope I do not offend anyone from the House of Representatives, but coming from the Senate, we think our bill is the best and we want it to serve as a model for reform.

At this point, I know of three bills which have been introduced in the House on separate subjects: drugs, devices, and food.[37] The Senate bill, our

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to the general public has since been taken out of reform legislation due to disagreement over the wording of the provisions. S. REP. NO. 284, 104th Cong., 2d Sess. 220 (1996).

35. Senator Dodd (D-CT); Senator Harkins (D-IA); and, almost, Senator Wellstone (D-MN).

36. The bill was introduced in the Senate on Dec. 13, 1995 and reported in the Senate on June 20, 1996.

37. The Clinton Administration is much more concerned with the House bills. The House bills are more radical, if you will, than our bill. Our bill is a more moderate proposal. Thus, I anticipate there will be some fireworks. It is conceivable that, for instance, just the device portion of our bill could pass the House. Then we could go to conference with the device bill on the House side, all of our bill. Then we could pick up the Senate provisions on drugs, biologics, animal drugs, etc. and compromise on the device portions. It is hard to predict at this

bill, briefly addresses speeding up the review process for food additives.[38] The food issues appear to be very contentious. They center around reforming the Delaney Clause,[39] which affects pesticides and food additives. The Delaney Clause, which was adopted in the 1950s, is one of those examples of how science has far outstripped the regulatory process. Essentially, everyone agrees that the Delaney Clause needs to be reformed, but no one knows exactly how. In fact, we have had many constituents contacting us and warning us not to support any food reforms. During committee action, Senator Gregg (R-NH), wanted to offer three food amendments, but he graciously backed-off when Senator Mikulski and others warned him that if such amendments were added to our bill, they would torpedo FDA reform this year. It remains to be seen how that will work out. It is certainly conceivable that the House could pass their device bill. I read in *Congress Daily* that the House is planning committee action this month and maybe the first week in June.

I truly think that we can succeed in FDA reform, and this is the time to do it. This is the window of opportunity. Senator Kassebaum is retiring at the end of the year and would really like to see this bill pass. However, we have a very short legislation session. Practically speaking, we have less than 90 days to get anything done because this summer we have the Olympics and no one will be paying much attention to what is happening on the Hill. Then in August, we have the Democratic and Republican conventions. Congress will return in September, mess around with appropriations, and hopefully get a budget this year. They are projecting to adjourn on October fourth because it is a presidential and congressional election year. By then, we are already into December. So, we must act now; we must pass these bills now.

The point to all of this is that if we are going to reform the FDA, we must do it now. We will certainly count on all the members of the biotechnology industry, as we have enjoyed their support in educating others about the importance of FDA reform. If our efforts are going to succeed, we

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point, but it will be interesting–I can assure you of that.

38. *See* S. 1477, 104th Cong., 2d Sess. § 801.

39. 21 U.S.C. § 348 (1996).

> The [Delaney] clause forbids any chemical residue on processed food that is found to "induce cancer when ingested by man or animal." 21 U.S.C. § 348(c)(1994). The Food and Drug Administration attempted to allow a *de minimis* level of risk from residues left by food coloring, but the courts found that the strict statutory language of the Delaney Clause would not allow *de minimis* risks without statutory changes. Public Citizen v. Young, 831 F.2d 1108, 1112 (D.C. Cir. 1987). The final blow came when the Ninth Circuit held that the EPA overstepped its statutory authority by allowing a *de minimis* risk given the purpose of the Delaney Clause. Les v. Riley, 968 F.2d 985, 990 (9th Cir. 1992). This zero-risk limit precludes any consideration of cost.

March Sadowitz, Note, *Tailoring Cost-Benefit Analysis to Environmental Policy Goals: Technology- and Health-Based Environmental Standards in the Age of Cost-Benefit Analysis*, 2 B.U. J. SCI. & TECH. L. 11, para. 25 n.104 (1996).

must dispel the rumors that this bill could harm patients. Senator Mikulski simply would not have supported it if that were the case.